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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,147	09/22/2003	Shin Sadano	2003_0988A	5797

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EXAMINER
DRODGE, JOSEPH W

ART UNIT	PAPER NUMBER
1723	

DATE MAILED: 11/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/665,147	SADANO ET AL.	
	Examiner	Art Unit	
	Joseph W. Drodge	1723	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *15-21* is/are allowed.

6)☒ Claim(s) *22-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 22-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kumar patent 6,737,535 in view of Sakato patent 5,288,550.

Kumar discloses marigold oleoresin product which has been purified by solvent extraction with a ketone or other solvent and by filtration techniques, contains a high level of lutein fatty acid ester content and may be in the form of a soft gelatin capsule and thus have a low viscosity (column 4, lines 50-63, column 5, lines 26-48 and column 5, line 65-column 6, line 2). The lutein content well exceeds the claimed 20 or 30 percent recited in claims 22 and 23 when purified (See Examples) and the disclosed conversion into soft gelatin capsule form inherently lowers the viscosity to below the claimed values. ***The product may be obtained in a capsule or soft gelatin or liquid form (column 5, line 65-column 6, line 2, also column 10, line 34).***

With respect to claim 28, the product consists essentially of purified marigold resin, since there may only be a very small ratio of solvent to marigold resin present with the solvent not affecting the food/nutritional or medicinal properties, such as bioavailability, of the product (Kumar (column 10, lines 28-34 or column 3, lines 48-62).

The claims may optionally be deemed to differ in requiring the purified product to have a specific lowered viscosity. However, Sakato teaches that when pharmaceutical or health/vitamin supplement is dissolved in a ***small amount of (column 2, lines 44-47, column 4, lines 50-54 and Tables of column 3)*** hydrophilic solvent, such as acetone or other ketones (column 2, lines 64-65) and then enclosed in a soft gelatin capsule, the viscosity is lowered dramatically (especially column 1, lines 14-21, column 2, lines 26-42 and 57-68 and Tables 1-4 of column 3). It would have been obvious to one of ordinary skill in the art to have modified the product of Kumar by lowering its velocity when converted into soft gelatin capsule form, as taught by Sakato, in order to ease production problems in manufacturing the capsule, enabling more efficient production of the capsules {such motivation suggested at column 1, lines 26-68 of Sakato}, as well as, inherently, to make the product easier to swallow and digest. Particular viscosity values are shown in the Examples of Sakato.

When the reference teaches a product that appears to be the same as, or an obvious variant of, the product set forth in a product-by-process claim although produced by a different process, the burden of proof is shifted to applicant to establish that their product is patentably distinct and not the examiner to show the same process as making. See In re Marosi, 710 F.2d 799, 218 USPQ 289 (Fed. Cir. 1983) and In re Thorpe, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985). Also see *In re Brown*, 173 USPQ 685 and *In re Fessmann*, 180 USPQ 324 and MPEP 2113.

ALLOWABLE SUBJECT MATTER

Independent claim 16 and thus all claims dependent therefrom remain distinguished in view of recitation in claim 16 of the process of producing purified marigold oleoresin comprising 1st dissolving in a ketone solvent followed by cooling and precipitating and concentration then subjecting the concentrate to a supercritical fluid extraction. All of the prior art of record only teaches using first a supercritical fluid extraction step followed by a later organic or ketone solvent extraction step.

Independent claim 15 and claims dependent therefrom are now also deemed to distinguish, in view of recitation of dissolving the residue of a supercritical fluid extraction step in a ketone solvent, as argued in the Remarks of September 27, 2006.

Applicant's arguments filed on September 27, 2006, with respect to claims 22-28 concerning the rejection based on Kumar in view of Sakato, have been fully considered but they are not persuasive.

It is argued that Kumar only discloses manufacture of a solid marigold resin product. However the product is explicitly recited as being obtained in a capsule or soft gelatin or liquid form (Kumar at column 5, line 65-column 6, line 2 and column 10, lines 34).

It is argued that the claims are drawn to viscosity of marigold resin, without the presence of solvent. None of the instant claims preclude presence of a small amount of solvent or other substance with the marigold resin.

Sakato teaches that when pharmaceutical or health/vitamin supplement is dissolved in even a ***small amount of (column 2, lines 44-47, column 4, lines 50-54 and Tables of column 3)*** hydrophilic solvent, such as acetone or other ketones (column 2, lines 64-65) and then enclosed in a soft gelatin capsule, the viscosity is lowered dramatically (especially column 1, lines 14-21, column 2, lines 26-42 and 57-68 and Tables 1-4 of column 3). Since ***the product consists essentially of purified marigold resin, since there may only be a very small ratio of solvent to marigold resin present with the solvent not affecting major basic material properties of the composition including the food/nutritional or medicinal properties, such as bioavailability, of the product (Kumar (column 10, lines 28-34 or column 3, lines 48-62).***

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Drodge at telephone number 571-272-1140. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker, can reached at 571-272-1151. The fax phone number for the examining group where this application is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either private PAIR or Public PAIR, and through Private PAIR only for unpublished applications. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JWD

October 28, 2006

JOSEPH DRODGE
PRIMARY EXAMINER